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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,152	01/16/2001	Michelle A.J. Palmer	4085-235-27 CIP	2836

7590

06/10/2003

PIPER MARBURY RUDNICK & WOLFE LLP
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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/10/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/759,152

Applicant(s)

Palmer et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 20, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above, claim(s) 2-5, 11, 12, 14, 16, 17, 19-23, 30-47, and 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 6-10, 13, 15, 18, 24, 25, 29, 48-50, and 54 is/are rejected.
- 7) ☒ Claim(s) 26-28 and 51-53 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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- 1) Claims 1 to 60 are pending in the instant application. Claims 1 to 26 have been amended and claims 27 to 60 have been added as requested by Applicant in Paper Number 17, filed 20 March of 2003.
- 2) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 March of 2003 has been entered.
- 3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5) Claims 2 to 5, 14, 30 to 47 and 55 to 60 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.
- 6) Claims 11, 12, 16, 17 and 19 to 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

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7) The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. The instant specification refers to the amino sequence "GGGGS" numerous times without employing the required sequence identifier. Correction is required. See M.P.E.P. 2422.03.

8) Applicant is advised that should claim 29 be found allowable, claim 54 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

9) Claims 6 to 8 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record as applied to claims 1, 6 to 13 and 15 to 25 in section 7 of Paper Number 11 and claims 6 to 8 in section 6 of Paper Number 14. As stated and repeated therein, a critical element of the disclosed invention is the requirement that each member of a pair of interacting proteins be fused to one member of a pair of complementary β -galactosidase mutants. This critical feature is **lacking from the instant claims**. Applicant's traversal of this rejection on the premise that the critical elements are provided by the instant specification and a general knowledge of the art completely ignores the basis upon which this rejection was made.

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10) Claims 1, 6 to 10, 13, 15, 18, 24, 25, 29, 48 to 50 and 54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the Blau et al. patent (6,342,345 B1) in view of the Barak et al. patent (5,891,646, cited by Applicant) the Kovoov et al. publication (J. Biol. Chem. 274(11):6831-6834, 12 Mar. 1999, cited by Applicant), the Gurevich et al. '95 publication (J. Biol. Chem. 270(2):720-731, 13 Jan. 1995, cited by Applicant) and the Gurevich et al. '97 publication (Mol. Pharm. 51:161-169, 1997) for those reasons of record as applied to claims 1, 6 to 10, 13, 15, 18, 24 and 25 in section 10 of Paper Number 12 and section 7 of Paper Number 14. Applicant's arguments in traversal of this rejection essentially repeat those arguments of record which were answered section 7 of Paper Number 14.

11) Claims 26 to 28 and 51 to 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Whereas the text in line 49 of column 11 of Blau et al. described the use of a linker to join a binding partner to one of the complementary β -galactosidase mutants described therein, the art of record did not disclose any advantage to employing the specific linker recited in the instant claims in the construction of such a fusion protein.

12) Applicant's arguments filed 20 March of 2003 have been fully considered but they are not persuasive for those reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800